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Dennis F. Armijo, Esq.
DENNIS F. ARMIJO, P.C.
6300 Montano Rd., NW
Suite D
Albuquerque, NM 87120

EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,766

Applicant(s)

SHAHINPOOR ET AL.

Examiner

Javier G. Blanco

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3, 7-9 and 11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 10, and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1-16 and 18-20 in the reply filed on September 13, 2004 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 2, 4-6, 10, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Regarding claim 1, newly added claim limitation "said natural zonular fibers comprise a means for transmitting a first contraction force" (see lines 5-6) was not disclosed/described in the specification and/or figures. Also, newly added claim limitation "said at least one bridge..... comprises a means for transmitting a second contraction force" (see lines 6-7) was not disclosed/described in the specification and/or figures. Claims 2, 4-6, and 10 depend on claim 1.

b. Regarding claim 18, newly added claim limitation "said natural zonular fibers comprise a means for transmitting a first contraction force" (see lines 7-8) was not disclosed/described in the

Art Unit: 3738

specification and/or figures. Also, newly added claim limitation "said at least three circularly distributed bridges.....comprises a means for transmitting a second contraction force" (see lines 9-10) was not disclosed/described in the specification and/or figures. Claims 19 and 20 depend on claim 18.

4. Claims 1, 2, 4-6, 10, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a. Regarding claim 1, newly added claim limitation "said at least one bridge.....comprises a means for transmitting a second contraction force" (see lines 6-7) is not enabling. After reading the specification, the Examiner concluded that none of the implant variations/species (elected species is embodied in Figures 9 and 11) presents "a means for transmitting" as required in claim 1. The specification does not disclose/describe said "means for transmitting" either. The specification discloses the implant variations/species as "force transmitting bridges" (see paragraphs 0076 and 0077). Claims 2, 4-6, and 10 depend on claim 1.

b. Regarding claim 18, newly added claim limitation "said at least three circularly distributed bridges.....comprises a means for transmitting a second contraction force" (see lines 9-10) is not enabling. After reading the specification, the Examiner concluded that none of the implant variations/species (elected species is embodied in Figures 9 and 11) presents "a means for transmitting" as required in claim 18. The specification does not disclose/describe said "means for transmitting" either. The specification discloses the implant variations/species as "force transmitting bridges" (see paragraphs 0076 and 0077). Claims 19 and 20 depend on claim 18.

Art Unit: 3738

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 4-6, 10, and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 1, newly added claim limitation "said natural zonular fibers comprise a means for transmitting a first contraction force" (see lines 5-6) is indefinite as to the scope of the invention. Claims 2, 4-6, and 10 depend on claim 1.

b. Regarding claim 13, "an eye lens" (see line 1) lacks antecedent basis. This was addressed in the past office action. Also, the way it is currently amended renders the claim vague and indefinite (i.e., "an eye lens comprises an implanted lens").

c. Regarding claim 14, "the at least one set of natural zonular fibers" (see lines 6-7) lacks antecedent basis. Claims 15-17 depend on claim 14.

d. Regarding claim 18, newly added claim limitation "said natural zonular fibers comprise a means for transmitting a first contraction force" (see lines 7-8) is indefinite as to the scope of the invention. Claims 19 and 20 depend on claim 18.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Art Unit: 3738

8. Claims 1, 2, 4-6, 10, and 18-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

a. Regarding claim 1, Applicants positively recite part of a human, i.e., "affixed to the at least one set of natural zonular fibers" (lines 6-7). Thus claim 1 include a human or living tissue within their scope and are non-statutory. Claim 2, 4-6, and 10 depends on claim 1. Examiner respectfully suggests Applicants to remove said limitation (i.e., "affixed to the at least one set of natural zonular fibers") from lines 6-7.

b. Regarding claim 18, Applicants positively recite part of a human, i.e., "affixed to the natural zonular fibers" (lines 9-10). Thus claim 18 include a human or living tissue within their scope and are non-statutory. Claim 19 and 20 depends on claim 18. Examiner respectfully suggests Applicants to remove said limitation (i.e., "affixed to the natural zonular fibers") from lines 9-10.

A claim directed to or including within its scope a human or living tissue is not considered to be patentable subject matter under 35. U.S.C. 101. The living matter of the present invention is not the result of human intervention; it is of nature, which has been held not patentable. The grant of a limited, but exclusively property right in a human being is prohibited by the Constitution. In re Wakefield, 422 Fed.Cir.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Art Unit: 3738

10. Claims 1, 2, 4-6, 10, and 14-17 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ganem et al. (CA 2 358 485 A1).

Referring to Figures 1, 2, and 4, Ganem et al. disclose an apparatus *for* augmenting near vision accommodation by contraction of the ciliary muscles by contraction of the ciliary muscles of the eye by reinforcement (see page 1, lines 15-18 and lines 22-24) of at least one set of natural zonular fibers, the apparatus comprising at least one bridge (ring or device 20) *configured to be* affixed (see Figure 2) to the at least one set of natural zonular fibers, wherein said at least one bridge transmit an augmented contraction force for constricting the natural crystalline lens (see page 2, lines 3-6; see claim 1).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganem et al. (CA 2 358 485 A1).

Ganem et al. disclose the invention as claimed except for at least three bridges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have at least three bridges, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Art Unit: 3738

Response to Arguments

13. Applicant's arguments with respect to claims 1, 14, and 18 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

14. Claim 12 is allowed.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



December 8, 2004



David H. Willse
Primary Examiner